REMARKS

Claims 9-10 are amended. Claims 1-8, 11-25, 28-42, and 45-72 are unchanged.

The Office Action Summary incorrectly identifies Claims 1-72 as being pending. On May 15, 2003, Applicants mailed an Amendment Under 37 C.F.R. § 1.111, in which Claims 26-27 and 43-44 were canceled. Thus, Claims 1-25, 28-42, and 45-72 are pending.

THE AMENDMENT

Claims 9 and 10 have been amended to recite that the dosage form is *rapid-release*, rather than *immediate release*. Support therefor can be found, for example, at page 5, line 28 of the Specification. This amendment was prompted by the Examiner in a telephone conversation on June 22, 2004 and was to be attended to by an Examiner's amendment, which was to accompany a Notice of Allowance. Since an Office Action was issued instead of the Notice of Allowance, Applicants wish to make the amendment now. Applicants submit that the amendment does not change the substance of the claims, and is made solely for purposes of clarification.

No new matter has been added.

THE INVENTION

Claim 1 recites a method for treating premature ejaculation. A rapid-release pharmaceutical formulation is administered less than 3.5 hours prior to anticipated sexual activity, and the formulation releases an antidepressant drug at a rate that provides a systemically effective level of the drug within 3.5 hours of administration.

Claim 40 recites a pharmaceutical formulation for treating premature ejaculation. The formulation comprises a rapid-release formulation that releases an antidepressant at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration.

Claim 71 recites a packaged kit for the treatment of premature ejaculation. The kit comprises a rapid-release pharmaceutical formulation that releases an antidepressant at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration to a patient.

The claimed method, formulation and kit relate to an as-needed basis administration, with "as-needed basis" defined in the specification to mean that the method does not involve chronic

pharmacotherapy. The claims all recite that the antidepressant drug is selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, monoamine oxidase inhibitors, azaspirone antidepressants, and atypical non-SRI antidepressants.

REJECTION UNDER 35 U.S.C. §102(b) OVER EL-RASHIDY

Claims 1-24, 40-41, 50-54, 57-58, and 61-72 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,830,500 to El-Rashidy et al. (hereinafter "El-Rashidy").

El-Rashidy is cited as disclosing a direct compression tablet for the rapid release of fluoxetine. The Examiner notes that the tablet releases 50 wt% of the fluoxetine in about one minute. The Examiner further indicates that the El-Rashidy disclosure incorporates by reference the teaching regarding the use of fluoxetine for the treatment of premature ejaculation.

As noted above, independent Claims 1, 40 and 71 all recite that the antidepressant drug is selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, monoamine oxidase inhibitors, azaspirone antidepressants, and atypical non-SRI antidepressants.

Anticipation of a claimed invention by a prior art reference under 35 U.S.C. §102(b) requires the presence in a single prior art reference of each and every element of a claimed invention. Applicants submit that Claims 1, 40 and 71, and the claims that depend therefrom, are not anticipated by the El-Rashidy reference since El-Rashidy does not disclose nor suggest the recited classes of antidepressant drugs - tricyclic antidepressants, tetracyclic antidepressants, monoamine oxidase inhibitors, azaspirone antidepressants, and atypical non-SRI antidepressants.

The El-Rashidy teaching is specific to the drug fluoxetine. No other drugs are taught or suggested. Fluoxetine, while an antidepressant, is a serotonin reuptake inhibitor. Serotonin reuptake inhibitors are not considered to be tricyclic antidepressants, tetracyclic antidepressants, monoamine oxidase inhibitors, azaspirone antidepressants, or atypical non-SRI antidepressants, which are the claimed classes of antidepressant drugs. Therefore, Applicants submit that fluoxetine *does not* fall under any of the claimed antidepressant classes. Further, Applicants submit that serotonin reuptake inhibitors are not even suggestive of the recited classes of antidepressants.

The Examiner's attention is directed to page 6, lines 7-14, of the Specification, which distinguishes fluoxetine from the claimed classes of antidepressant drugs by stating:

> "In a first aspect of the invention, a method is provided for the treatment of an individual prone to or suffering from premature ejaculation, the method comprising systemically administering to an individual in need of such treatment a therapeutically effective amount of an antidepressant drug selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, azaspirone antidepressants, MAOIs, and other non-SRI antidepressants. *In contrast to serotonin reuptake inhibitors such as paroxetine, sertraline, and fluoxetine, the present agents do not exhibit any significant side effects and do not require chronic administration for effectiveness*". [emphasis added]

Therefore, Applicants submit that Claims 1, 40 and 71, and the claims that depend therefrom, are not anticipated by the El-Rashidy reference. In addition, with regard to the method recited in Claim 1, there is an additional claimed feature that is not taught by the art. Claim 1 recites that administration is less than 3.5 hours prior to anticipated sexual activity. In contrast, the El-Rashidy reference describes daily administration of the fluoxetine (col. 3, lines 14-22) for eight weeks (col. 3, lines 26-29), before the drug can be taken on an as needed basis. And, even then, the "as per need" or precoital dosage is taken for an "extended period of time", as required (col. 3, lines 29-31). The claimed method relates to an as-needed basis administration, with "as-needed basis" defined in the specification to mean that the method does not involve chronic pharmacotherapy, such as is described in the El-Rashidy reference. While the formulation and kit claims do not have the "administering" language, Claims 40 and 71 do recite that the dosage form provides a systemically effective level of the drug within 3.5 hours of administration.

Accordingly, since El-Rashidy does not teach or suggest the invention as presently claimed, Applicants assert that the invention is patentable under 35 U.S.C. §102(b).

OBJECTED TO CLAIMS

The Examiner has indicated that Claims 25-39, 42-49, 55-56, and 59-60 are objected to as being dependent upon a rejected claim. As noted above, Claims 26-27 and 43-44 were previously canceled. Thus, the objected to claims are more correctly identified as being Claims 25, 28-39, 42, 45-49, 55-56, and 59-60.

SUMMARY

The above arguments and amendments to the Claims are submitted for the purpose of facilitating allowance of the Claims and a sincere effort has been made to place this application in condition for allowance. An early notice of allowance is earnestly requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 330-4916.

Respectfully submitted,

By: Shelley Eberle

Shelley R. Eberle
Registration No. 31,411

REED & EBERLE LLP
800 Menlo Avenue, Suite 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile

F:\Document\9050\0048\20\Amendment 1.111 (RCE).DOC